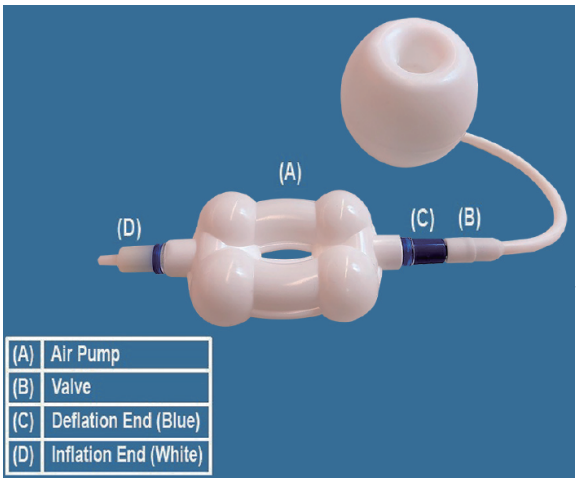
# Instructions for Use
# Silicone Inflatable Donut Pessary MD




**Not made with natural rubber latex**

## Description:

Inflatable Donut Pessaries are constructed of a compression molded silicone rubber with white pigment rubber colorant. They are non-toxicity, and the colorant is mainly made up of titanium dioxide. It is subject to specific FDA regulation, and the ratio of the addition is complied with regulation. Inflatable Donut Pessary is for single-patient use silicone pessary for mild cystocle and/or rectocele associated with procidentia/prolapse.They are four different size available shown below. It is necessary to have available a minimum of two size.

| SKU | ID2 REF | ID3 REF | ID4 REF | ID5 REF |
|---|---|---|---|---|
| Size | 51mm | 57mm | 64mm | 70mm |
| Suggested Number of Squeezes | 1 | 2 | 3 | 4 |

**IMPORTANT**

**DO NOT OVER INFLATE.** See suggested number of squeezes. Overinflation will weaken silicone. If your pessary "Balloon" out, it is an indication that it has been overinflated and you need a large size Inflatable Donut Pessary.

## Indications:

1. The inflatable Donut Pessary is effective suppport in second- or third-degree prolapsed, and also effective in patients with mild cytocele or recocele associated with a procidentia/prolapsed.
2. Support of Inflatable Donut Pessary can be adjusted based on the its inflation level.

   Note:

   **(1) Experience has shown that in order to properly fit an Inflatable Donut Pessary, you should have at least one of two most commonly used sizes of this pessary (size 57 (ID3) and 64 (ID4)).**

   **(2) The physician may suggest K-Y jelly ®, Replens® or equivalent, if you need to use lubricant.**

## Contraindications:

1. Do not use during pregnancy because of the risk of air embolism.
2. Inflatable Donut Pessary is contraindicated in acute genitial tract inflections, endometriosis, or non-compliant patients.
3. Sexual intercourse is contraindicated with Inflatable Donut Pessary in place.

## Caution:

1. This device to be sold by or on the order of a physician.
2. The device is for single patient use only. Do not share your device with others.
3. If the pessary is uncomfortable, please stop using and notify your doctor.

## Fitting Instructions For The Physician:

1. Inflatable Donut Pessary is fitted by trial and error. There are no mechanical devices available that can accurately determine the size your patient requires to obtain the desired results.
2. Fitting diaphragms should not be used to measure the size pessary a patient need.
3. Even before fitting a pessary, the patient should be informed that it is not uncommon to have to change the size more than once after being originally fitted. This is why it is so important that your patient be instructed to return within 24 hours of the initial fitting and again in 72 hours. Thereafter, re-examination every few months is recommended to ensure a proper fit is maintained as long as the patient is wearing the pessary.
4. At each visit the pessary should be removed and the vaginal vault inspected for signs of allergic reaction or undue pressure.
5. At the physician's discretion, the patient can be instructed in the proper removal, cleaning and reinsertion techniques for her own pessary. This process can be performed nightly by patient under ideal condition.
6. A noncomplian patient should not be fitted with Inflatable Donut Pessary. It is essential that your patient understands the importance of these frequent follow-up visits and that she fully cooperates with you to ensure the desired results.

## Prior To Fitting:

**Have the patient empty her bladder before fitting the pessary.**

Ulcerations and erosions frequency occur in cases of complete prolapsed due to irritation of the exteriorized cervix.

Whenever possible, reducing the mass and treating the irritation are primary steps before using a pessary.

The Inflatable Donut Pessary is designed for ease of insertion and removal by the patient. The pessary is inserted Deflated.

## Instruction For Use:

Perform a normal pelevic examination before inserting or fitting of the pessary. A first approximation of size can be made by using fingers to determine the approximate width of the vaginal vault. This will generally get you within size or two of proper pessary.

**Note: If necessary, irrigate the vagina prior to insertion of the pessary. This will cleanse the vagina of excess discharge and secretions.**

Figure 1

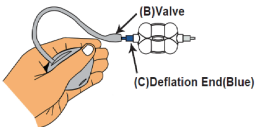
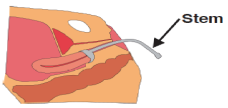



Figure 2

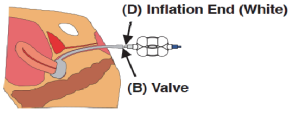



1. Deflate the air inside the Pessary completely before insertion. **(See Figure 1)**

   **Step (1) Attach Deflation End (C) to Valve (B) .**

   **Step (2) Press the Air Pump (A) to deflate the air inside the device.**
2. Gently insert the clean device into the posterior vagina beneath the cervix. The stem should protrude outside the vagina. **(See Figure 2)**

Figure 3




3. Attach the Inflation End (D) to the Valve (B) to inflate the Inflatable Donut Pessary with sufficient air as needed. **(Figure 3)**

   **WARING : DO NOT over inflate the Inflatable Donut Pessary to avoid causing any damage or/ and pain to the vagina.**
4. Detach the Inflation End (D) from the Valve (B). Gently place the stem into the vaginal vault.
5. If the patient is fitted using the physician's fingers and a ruler, and the patient returns after a day or more of use and complains the pessary either falls out (too small) or is painful and difficult to place (too large), the patient should be advised to use another pessary of different size.

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6. Once in place, the patient sit, stand and bear down. Examine the patient while she is in the standing position to ensure the pessary has not shifted position. The pessary should not to be too loose as it may turn or be expelled, and it should not be too tight as it may caused discomfort.
7. The physician should be able to sweep on finger between the pessary and vaginal walls. It there is not enough space to do this, the next smaller pessary should be tired. If excessive space exists, the pessary will not be effective and may rotate or even be expelled.
8. It is sometimes necessary to refit the patient with a differnt size after period of time. Check the fitting to ensure continued patient comfort and relief of symptoms. The shelf-life of device may be used for up to one year under normal use conditions.Examine frequently for aigns of deterioration.
**DO NOT assume that replacement will always be the same size as the previous one.**

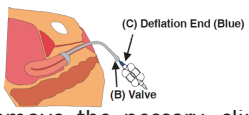
## Patient Follow-up

1. Toxic Shock Syndrome (TSS) is considered a serious and sometimes fatal disease caused by toxin-producing strains of Staphylococcus aureus bacterium. TSS has been linked to high absorbency and prolonged use of tampons. Symptoms of TSS often mimic the flu and can include sudden high fever, vomiting, diarrhea, dizziness, fainting or a rash that looks like sunburn during menstruation or a few days after. Patients should be counseled that if they experience any of these symptoms while using the pessary, remove it and immediately contact their physician.

2. Have the patient:
(a) Report immediately any difficult in urinating
(b) Report immediately any discomfort
(c) Return within 24 hours for first examination
(d) Return for second examination within 3 days
(e) Return at 4 to 6 week intervales, at which time the pessary is removed, cleaned, and if there are no contraindications, reinserted.
**Note: Above schedule of follow-up examinations may be altered to fit the needs of the individual patient.**

## Removal:

Figure 4




1. To remove the pessary, slip stem of pessary out of vagina. Attach the Deflation End (C) to Valve (B) (See Figure 4). Squeeze as suggestion then grasp the deflaed pessary and withdraw.
**WARNING: DO NOT pull the stem directly to remove the device from patient's vagina; this action may rupture the device.**
2. During each vist, the vagina should be carefully inspected for evidence of pressure or any reaction. The patient should be questioned concerning discharge, disturbance of bowel function or urination. It may be necessary to fit another size.
3. At each checkup, the pessary is removed and cleaned.

## Cleaning:

1. Prior to initial use, the Vaginal Pessary must be washed thoroughly.
2. Rinse Pessary with 20 - 40 °C warm water for 30-40 seconds.
3. Apply mild pH5-9 soap to rub the pessary gently back and forth for 10 times to lather well.
4. Rinse off Pessary with warm water for 1 minute, repeat and wash if needed.
5. Wash again and rinse Pessary thoroughly with distilled water for 1 minute. Ensure all traces of soap are removed to avoid irritation.
6. Allow to completely air-day before the reinsert.

NOTE:
**1. The Inflatable Donut Pessary should be periodically check for deep cracks or discoloration that make adequates cleaning impossible.**
**2. Do not immerse air pump of Inflatable Donut Pessary in water or any solutions to avoid malfunction.**

## Disposal Instructions

- When the pessary becomes damaged, discolored, deformed, or no longer clinically indicated, it should be disposed of in accordance with local regulations for medical waste.
- Used pessaries that have been in contact with bodily fluids should be handled as clinical waste. Place the used device in a sealed plastic bag or container before disposal to minimize contamination.
- If the device has not been in contact with infectious material (e.g., trial-fitted, unused, or clean pessary), it may be discarded as general non-hazardous waste, following hospital or clinic policy.
- Follow institutional and national environmental safety guidelines when discarding the device and its packaging materials.

## Storage & Transportation Conditions

- The device is 3 years from the date of manufacture.
- Store in a clean, dry environment with a temperature between 10–40°C and relative humidity between 30–80% RH.
- The device contains no sensitive materials, liquids, or gases, and is not considered precision machinery.
- It should be transported under normal atmospheric conditions in accordance with the manufacturer's recommendations to prevent damage.
- The transportation methods for export include truck, ship, and airplane, while inland transportation is primarily conducted by truck.

## Glossary of Symbols

| | | | |
|---|---|---|---|
| MD | Medical device | | Manufacturer |
| REF | Catalogue number | | Do not use if package is damaged and consult instructions for use |
| LOT | Batch code | 10°C 40°C | Temperature limit 10-40°C |
| | Expiry Date (YYYY/MM/DD) | 30% 80% | Humidity limitation 30-80%RH |
| | Caution | | Single patient multiple use |
| | Biological Risks | LATEX | Not made with Natural Rubber Latex |
| NON STERILE | Non sterile | 1 | Single patient multiple use |

## Reporting of Serious Incidents

If a serious incident related to the device occurs, immediately report the incident to **Bioteque Taiwan Ltd.** and to the applicable competent authority having jurisdiction in their locale.

**Bioteque Taiwan Ltd.**
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